Caprylic and Capric Acid (128919; 128955)

Tier I Acute Toxicity Tests: Primary Eye Irritation (OCSPP 870.2400), Primary Dermal Irritation (OCSPP 870.2500), Skin Sensitization (OCSPP 870.2600)

Submitter:	W. Neudorff GmbH KG An der Muhle 3 Emmerthal, 31860 Germany
Study Completion Date:	July/02/2019
MRID(s):	EP: 50886504; 50886505; 5094901
Primary Review:	Baylor Steele, Biologist, BPPD/RAB
Secondary Review:	Russell Jones, Ph.D., Senior Scientist, BPPD/RAB

WILLIAM STEELE Digitally signed by WILLIAM STEELE Date: 2020.03.05 13:59:16 -05'00'

Russell S. Jones, Ph.D. Digitally signed by Russell S. Jones, Ph.D. Date: 2020.03.10 07:29:37 -04'00'

STUDY TYPE: Primary Eye Irritation - NW Rabbit; OPPTS 870.2400; OECD 405

TEST MATERIAL:
Homeplate RTU (26.20% Caprylic acid and 21.7% Capric acid)
CAS# 124-07-2; 334-48-2
Lot/ Batch # DSA32-45-1

SYNONYMS: None given.

CITATION: Durando J., 2019. Homeplate RTU: Primary eye irritation in rabbits. Product Safety Labs, 2394 US Highway 130, Dayton, NJ 08810. Laboratory study number 50696, July 02, 2019. Unpublished. MRID 50886504.

SPONSOR: W. Neudorff GmbH KG., An der Muhle 3, Emmerthal, 31860, Germany

EXECUTIVE SUMMARY: In an acute eye irritation study (MRID 50886504), undiluted test substance (0.1 mL) placed into the conjunctival sac of the right eye of three healthy female Albino New Zealand White rabbits (Robinson Services Inc; Mocksville, NC) weighing 2.26-2.29 kg. Untreated left eyes served as comparative controls, and grades of ocular reaction were recorded at ~1, 24, 48,72, and 96 hours after treatment. Irritation was scored in accordance with the Draize method of scoring (Draize et al., 1944). The time interval with the highest mean score (Maximum Mean Total Score - MMTS) for all rabbits was used to classify the test substance by the system of Kay and Calandra (Kay & Calandr1t 1962).

Within 24 hours after test substance instillation, all three treated eyes exhibited corneal opacity and 'positive' conjunctivitis. There was no iritis observed in any treated eye during this study. The overall incidence and severity of irritation decreased gradually with time. Positive initation cleared from all three treated eyes by 72 hours. All animals were free of ocular irritation by Day 4 (study termination).

The Maximum Mean Total Score of Homeplate RTU is 16.3. Under the conditions of this study. Homeplate RTU is classified as mildly irritating to the eye.

This study is classified as acceptable. It does satisfy the guideline requirement for a primary eye irritation study (OPPTS 870.2400; OECD 405) in the rabbit.

COMPLIANCE: Signed and dated GLP, Quality Assurance, and Data Confidentiality statements were provided.

RESULTS AND DISCUSSION:

Observations	Number "positive"/number tested							
	Hours				Days			
	1	24	48	72	4	7*	10	12
Corneal Opacity	0/3	3/3	0/3	0/3	0/3	N/A	N/A	N/A
Iritis	0/3	0/3	0/3	0/3	0/3	N/A	N/A	N/A
Conjunctivae	3/3	2/3	1/3	0/3	0/3	N/A	N/A	N/A

*Study was ended after 4 days of observation, because there was no evidence of irritation by day 4.

A. Observations: Ocular irritation was evaluated using a white light source in accordance with the Draize method of scoring (Draize et al., 1944; see Table 4) at 1, 24, 48, and 72 hours and at 4 days post instillation. The fluorescein dye evaluation procedure was used in the treated eye at 24 hours and as needed at subsequent scoring intervals to evaluate the extent of corneal damage or to verify reversal of effects. One drop of ophthalmic fluorescein sodium dye was instilled into both eyes of each rabbit. The eyes were rinsed with physiological saline (0.9% NaCl) after instillation of the fluorescein and then evaluated for corneal damage using an ultraviolet light source. Individual scores were recorded for each animal. In addition to observations of the cornea, iris and conjunctivae, any other observed lesions were noted. The average score for all rabbits at each scoring period was calculated to aid in data interpretation. The maximum irritation score of 16.3 was used to rate the test substance as mildly irritating.

B. Reviewer's Conclusions: Based on the Maximum Mean Total Score (MMTS) of 16.3 (Kay and Calandra, 1962) at one-hour post instillation, the test substance is mildly irritating to the eye. The test substance is classified in EPA Toxicity Category III for primary eye irritation. This primary eye irritation study was conducted in accordance with the guideline recommendations for a primary eye irritation study (OCSPP 870.2400; OECD 405) in the rabbit.

C. Deficiencies: No deficiencies were noted

STUDY TYPE: Primary Dermal Irritation - NW Rabbit; OPPTS 870.2500; OECD 404

TEST MATERIAL:
Homeplate RTU (26.20% Caprylic acid and 21.7% Capric acid)
CAS# 124-07-2; 334-48-2
Lot/ Batch # DSA32-45-1

SYNONYMS: None given.

CITATION: Durando J., 2019. Homeplate RTU: Primary skin irritation in rabbits. Product Safety Labs, 2394 US Highway 130, Dayton, NJ 08810. Laboratory study number 50696, July 02, 2019. Unpublished. MRID 50886505.

SPONSOR: W. Neudorff GmbH KG., An der Muhle 3, Emmerthal, 31860, Germany

EXECUTIVE SUMMARY: In an acute dermal irritation study (MRID 50886505), 3 female Albino New Zealand White rabbits (Robinson Services Inc; Mocksville, NC) weighing 2.43 – 2.48 kg were dermally exposed to 0.1 ml of undiluted test substance on one intact test site (6 cm^2) per animal. The application area was covered with a 1-inch x 1-inch, 4-ply gauze pad and maintained in contact with the skin for 4 hours. Observations for dermal irritation and defects were made at 0-60 minutes, 24, 48, 72 hours, and 7 days after unwrapping. Irritation was scored by the method of Draize et al. 1944.

In this study, the test substance is not dermally irritating. Based on the Primary Dermal Irritation Scoring Scale (0.8), the test substance is rated as slightly irritating. Therefore, the test substance is assigned EPA toxicity category IV.

This study is classified as acceptable. It does satisfy the guideline requirement for a primary dermal irritation study (OPPTS 870.2500; OECD 404) in the rabbit.

COMPLIANCE: Signed and dated GLP, Quality Assurance, and Data Confidentiality statements were provided.

RESULTS and DISCUSSION:

Animal Number	Sex	Skin Irritation (Erythema/Edema) Following Patch Removal						
		30-60 minutes*	Hours			Days**		
			24*	48*	72*	7	10	14
3501	Female	0/0	0/0	0/0	0/0	0/0		
3502	Female	1/1	1/0	0/0	0/0	0/0		
3503	Female	1/1	2/1	1/0	1/0	0/0		
Severity of Irritation: Mean Score		0.7/0.7	1.0/0.3	0.3/0.0	0.3/0.0	0/0		

* Used in calculation of Primary Irritation Index (PII).
** Observations concluded at 7 days.

A. <u>Observations</u>: After four hours of exposure to the test substance, observations for dermal irritation and defects were made at ~1, 24, 48, 72 hours, and 7 days. Slightly dermal irritation was observed during the study.

B. <u>Results</u>: The primary irritation index (PII) of 0.8 out of 8.0 was obtained from observations at ~1, 24, 48, 72 hours, and 7 days of observation.

C. <u>Reviewer's Conclusions</u>: Based on the PII of 0.8, the test substance is slightly irritating. The test substance is classified in EPA Toxicity Category IV for primary dermal irritation. This study was conducted in accordance with the guideline recommendations for a primary dermal irritation study (OCSPP 870.2500; OECD 404) in the rabbit.

D. <u>Deficiencies</u>: No deficiencies were noted.

Reviewer: Baylor Steele, Biologist, BPPD/RAB
STUDY TYPE: Dermal Sensitization - Guinea Pig; OPPTS 870.2600; OECD 406

TEST MATERIAL (% a.i.):
Homeplate RTU (26.20% Caprylic acid and 21.7% Capric acid)
CAS# 124-07-2; 334-48-2
Lot/ Batch # DSA32-45-1

SYNONYMS: None given.

CITATION: Durando J., 2019. Homeplate RTU: Dermal Sensitization Test in Guinea Pigs. Product Safety Labs, 2394 US Highway 130, Dayton, NJ 08810. Laboratory study number 50696, July 02, 2019. Unpublished. MRID 50904901.

SPONSOR: W. Neudorff GmbH KG., An der Muhle 3, Emmerthal, 31860, Germany

EXECUTIVE SUMMARY: In a dermal sensitization study (MRID 50904901), 30 Hartley-Albino Guinea Pigs weighing 378 – 454 g were tested using a modification of the Buehler method (Ritz, HL, and Buehler, EV, "Planning, Conduct, and Interpretation of Guinea Pig Sensitization Patch Tests", Current Concepts in Cutaneous Toxicity, p. 25-42, Academic Press, NY, 1980) with HCA as a positive control material. The positive control group was tested in a separate study that was initiated within six months of the definitive study. Test group animals were treated with 0.4 mL of undiluted test substance (selected from range-finding) once weekly for three weeks, for a total of three inductions.

The test substance produced no reaction in either Test animals or Naive control animals after the challenge treatment. Therefore, Homeplate RTU is not a sensitizer in guinea pigs.

This study is classified as acceptable. It does satisfy the guideline requirement for a dermal sensitization study (OPPTS 870.2600; OECD 406, 429) in the Guinea pig.

COMPLIANCE: Signed and dated GLP, Quality Assurance, and Data Confidentiality statements were provided.

I. PROCEDURE

A. Irritation Range-Finding: Four albino guinea pigs were selected for irritation range-finding to determine the highest non-irritating concentration (HNIC) of the test substance prior to the challenge dose. Concentrations tested in the range-finder were 100% (undiluted), and 75%, 50% and 25% v/v dilutions in deionized (DI) water, with each animal receiving 0.4 mL of each concentration at different test sites.

B. Induction: Based on range-finding results, the dose administered was an application of 0.4 mL of undiluted test substance. For each induction treatment, the neat test substance was applied

to the left side of each test animal using an occlusive 25 mm Hill Top Chamber. The chambers were secured in place and wrapped with non-allergenic Durapore adhesive tape to avoid dislocation of the chambers and to minimize loss of the test substance for six hours. After the 6-hour exposure period, the chambers were removed and the test sites were gently cleansed with a 3% soap solution followed by tap water and a clean paper towel to remove any residual test substance. Approximately 24 and 48 hours after each induction application, readings were made of local reactions (erythema).

C. Challenge: Twenty-seven days after the first induction dose, four-tenths of a milliliter of the neat test substance (100%, HNIC) was applied to a naive site on the right side of each animal as a challenge dose, using the procedures described above. These sites were evaluated for a sensitization response (erythema) approximately 24 and 48 hours after the challenge application.

D. Naive Controls: In addition to the test animals, l0 guinea pigs from the same shipment were maintained under identical environmental conditions and were treated with the HNIC of the test substance at challenge only. These animals constituted the "naive control" group.

II. RESULTS and DISCUSSION:

A. Reactions and duration: Very faint erythema (0.5) was noted at one test site 24 hours following the third induction.

B. Positive control: Seven of ten positive control animals exhibited signs of a sensitization response (faint erythema) 24 hours after the challenge application. Positive responses persisted at five positive control sites through 48 hours. Very faint erythema (0.5) was noted at all other sites 24 and 48 hours after challenge application. The positive response observed in the historical positive control validation study with HCA validates the test system used in this study

C. Reviewer's Conclusions: Based on these findings and on the evaluation system used, the test substance is not a sensitizer in guinea pigs. This study was conducted in accordance with the guideline recommendations for a dermal sensitization study (OCSPP 870.2600; OECD 409) in the guinea pig.

D. Deficiencies: No deficiencies were noted.